

## RESIDUAL SOLVENT DECLARATION

**Product Name: Dibasic Calcium Phosphate Dihydrate, Dibasic Calcium Phosphate Anhydrous, Tribasic Calcium Phosphate and Calcium Carbonate**

TO WHOMSOEVER IT MAY CONCERN

Date: 02/01/2017

This is to confirm that “**Dibasic Calcium Phosphate Dihydrate, Dibasic Calcium Phosphate Anhydrous, Tribasic Calcium Phosphate and Calcium Carbonate**” is checked for Residual Organic Solvents according to USP General Chapter <467> / ICHQ3C / EP and hereby we confirm the following:

### 1. For Class 1 residual solvents:

Are class 1 (as per current version of ICH Q3C / USP <467>) solvents used or generated according to the above mentioned guidelines?

Yes		<b>No</b>	√
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If yes, please list the solvents concerned and their concentration limit in the Material complying to ICH Q3C / USP<467> Limit:

Name of the Class 1 Solvent	Vendor's Specification	Concentration limit in PPM (As per ICHQ3C / USP<467>)

### 2. For Class 2 residual solvents:

Are Class 2 (as per current version of ICH Q3C / USP <467>) solvents likely to be present according to the above mentioned guidelines?

(“Likely to be present” refers to the solvent used in the final manufacturing steps and to solvents that are used in earlier manufacturing steps and not removed consistently by validated process.)

Yes		<b>No</b>	√
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If yes, please list the solvents concerned and their concentration limit in the Material complying to ICH Q3C / USP<467> Limit:

Name of the Class 2 Solvent	Vendor's Specification (Concentration limit in PPM / % w/w)	Concentration limit in PPM / % w/w (As per ICHQ3C / USP<467>)

**3. For Class 3 residual solvents:**

Are Class 3 (as per current version of ICH Q3C / USP <467>) solvents likely to be present according to the above mentioned guidelines?

("Likely to be present" refers to the solvent used in the final manufacturing steps and to solvents that are used in earlier manufacturing steps and not removed consistently by validated process.)

Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>
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If yes, please list the solvents concerned and their concentration limit in the Material complying to ICH Q3C / USP<467> Limit:

Name of the Class 3 Solvent	Vendor's Specification (Concentration limit in PPM / % w/w)	Concentration limit in PPM / % w/w (As per ICHQ3C / USP<467>)

**4. For Any Other Residual Solvents:**

Are any other solvents likely to be present (e.g. solvents that are not covered under Class 1, Class 2 and Class 3 of as per current version of ICH Q3C / USP <467>)?

("Likely to be present" refers to the solvent used in the final manufacturing steps and to solvents that are used in earlier manufacturing steps and not removed consistently by validated process.)

Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>
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If yes, please list the Name of solvents and the in house limits.

Name of the Solvent	Vendor's Specification* (Concentration limit in PPM / % w/w)

\* \* – Provide the Justification for the Acceptance limit.

Thus, **Dibasic Calcium Phosphate Dihydrate, Dibasic Calcium Phosphate Anhydrous, Tribasic Calcium Phosphate and Calcium Carbonate** manufactured by us complies with Residual Organic Solvents requirements as per ICHQ3C, USP<467> and EP. We also hereby confirm that, any change in solvents used in manufacturing process will be intimated to you before shipment of consignment.

**FOR SUDEEP PHARMA PVT. LTD.**




**Senior- QA Manager**

DATE: 02/01/2017